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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,399

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Brian C. Case

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30565

7590

07/22/2010

Woodard, Emhardt, Moriarty, McNett & Henry LLP  
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EXAMINER

SHARMA, YASHITA

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

07/22/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketDept@uspatent.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,399	<b>Applicant(s)</b> CASE ET AL.	
	<b>Examiner</b> YASHITA SHARMA	<b>Art Unit</b> 3774	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 45-50 is/are pending in the application.
- 4a) Of the above claim(s) 3, 33-37 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 13, 14, 22, 26-32, 38-40, 42 and 45-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## **DETAILED ACTION**

### ***Status of Claims***

1. This office action is responsive to the amendment filed on 04/21/2010. As directed by the amendment: claims 2, 10, 11, 13, 14, 26-30, 38, 39 and 42 have been amended, claims 1, 4-9, 12, 15-25, 43 and 44 have been cancelled, claims 3, 33-37 and 41 have been withdrawn and new claims 45-50 have been added. Thus, claims 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 45-50 are presently pending in this application.

### ***Response to Arguments***

2. Applicant's arguments with respect to claims 2, 10, 11, 13, 14, 26-32, 38-40, 42 and 44 have been considered but are moot in view of the new ground(s) of rejection.

3. The requirement for election of subspecies regarding Figures 1A-1C has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the "barbs penetrate said first piece of

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flexible material," since they extend from the flexible material as claimed in claim 26 and disclosed in Fig. 2.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claims 2, 10, 11, 14, 26-32, 38-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in view of Lucatero et al. (2004/0087975) "Lucatero".**

8. Regarding claim 26 and 32, Pavcnik discloses a method for modifying blood flow in a vascular vessel, the method comprising: percutaneously delivering one or more pieces of flexible material having two or more leaflets (covering 45 or leaflets 78, 79; pg. 8, par. 0078) to a site within a vascular vessel (claim 21), said one or more pieces of flexible material including a first piece of flexible material (leaflets 78 and 79; Fig. 42) having a first edge (Fig. 42 shows the oval frame 11 edge of the leaflets 78 and 79), said first piece of flexible material having extending therefrom an array of vessel wall-penetrating elements extending longitudinally proximate said first edge (Fig. 43 shows barbs 124 extending from the first edge of the frame 11), and percutaneously attaching at least portions of said one or more pieces of flexible material to walls of the vascular vessel (claim 17) so as to form a structure that selectively permits blood flow in a first

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direction and resists blood flow in a second direction (claim 21), said percutaneously attaching including inherently driving vessel wall-penetrating elements of said array into a wall of the vascular vessel so as to secure a corresponding band of said first piece of flexible material to said vascular vessel wall (Pavcnik discloses anchoring the device within a lumen with the use of barbs; pg. 2, par. 0011); *except for* said array having a width extending in a direction inward of said first edge and having vessel wall penetrating elements occurring generally laterally with respect to one another in the direction of said width.

However, Lucatero teaches a similar device comprising an array of barbs 16 (Fig. 48) having a width fully capable of extending in a direction inward of said first edge and having vessel wall penetrating elements occurring generally laterally with respect to one another in the direction of said width (barbs 16 in Fig. 48 have two barb elements extending side by side to each on a metallic band). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the leaflet edge 11 (Fig. 43) in Pavcnik to include array having a width extending in a direction inward of said first edge and having vessel wall penetrating elements occurring generally laterally with respect to one another in the direction of said width, for the purpose of allowing the leaflet edge to securely grip the surrounding vessel tissue to prevent any slipping or sliding of the valve.

9. Regarding claims 2 and 14, as best understood, Pavcnik discloses the vessel wall-penetrating elements include barbs 124 (Fig. 43) (claim 17) that penetrate the first

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piece of flexible material (the barbs 124 extend from the edge of the flexible material as required by claim 26 and the drawings).

10. Regarding claims 10 and 11, Pavcnik discloses the first edge is a reinforced edge and the reinforced edge has a thickness greater than a central portion of said first piece (pg. 8, par. 0078) (Fig. 45). Pavcnik discloses "other layers of different materials can be laminated to or blended with the edge portion to provide desired properties," which allows for the reinforced edges that are thicker than the central portion of the flexible material or leaflet (pg. 8, par. 0078).

11. Regarding claims 27-31, Pavcnik discloses the first piece of material (leaflets 78 or 79; Fig. 42) has remodelable properties, contains collagen (pg. 8, par. 0078), and comprises an extracellular matrix material containing collagen and submucosa (pg. 5, par. 0067).

12. Regarding claims 38-40, Pavcnik discloses percutaneously delivering comprises deploying the one or more pieces of flexible material (leaflets 78 or 79; Fig. 42) from a lumen of a percutaneously advancable device (catheter or balloon; claims 17 and 18), deploying a delivery structure from the lumen, the delivery structure including the one or more pieces of flexible material (leaflets 78 or 79; Fig. 42) releasably held to an expandable element (par. 4, par. 0060; claims 18 and 19), wherein the expandable element includes a balloon (claim 17).

13. Regarding claim 42, Pavcnik discloses the band (lateral width of the frame 11; Fig. 42) is secured to the vascular vessel in a path extending at least partially

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longitudinally and at least partially circumferentially along the wall (as best shown in Figs. 48 and 49).

**14. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in view of Lucatero et al. (2004/0087975) "Lucatero" further in view of Ahn (5,843,170).**

Pavcnik in view of Lucatero discloses the claimed invention as discussed above; except for the vessel wall-penetrating elements include hooks. However, Ahn teaches a similar device comprising hooks 12 (Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Pavcnik in view of Lucatero to include hooks, for the purpose of securely anchoring the device in vessel walls.

**15. Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in view of Lucatero et al. (2004/0087975) "Lucatero" further in view of Dobben (4,99,077).** Pavcnik in view of Lucatero discloses the claimed invention as discussed above; except for barbs include microbarbs having a diameter ranging from about 0.0005 inches to about 0.100 inches, up to about 0.010 inches and at least about 0.005 inches. However, Dobben teaches a similar device comprising barbs having a diameter of 0.016 inches (col. 2, lin. 32-33). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Pavcnik in view of Lucatero to include barbs including microbarbs having a diameter ranging from about 0.0005 inches to about 0.100 inches, up to about 0.010 inches and at least

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about 0.005 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, **discovering the optimum or workable ranges** involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

16. **Claims 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pavcnik et al. (2009/0157169 continuing from at least 2/5/2001) "Pavcnik" in view of Lucatero et al. (2004/0087975) "Lucatero" further in view of Yang (2002/0138138).** Pavcnik in view of Lucatero discloses the claimed invention as discussed above; except for the barbs include microbarbs having a length ranging from about 0.001 inches to about 0.50 inches, up to about 0.100 inches and at least about 0.01 inches. However, Yang teaches a similar device comprising barbs having a length ranging from about 0.001 inches to about 0.50 inches, up to about 0.100 inches and at least about 0.01 inches (pg. 6, par. 0072). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the device in Pavcnik in view of Lucatero to include barbs including microbarbs having a length ranging from about 0.001 inches to about 0.50 inches, up to about 0.100 inches and at least about 0.01 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, **discovering the optimum or workable ranges** involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP



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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to YASHITA SHARMA whose telephone number is (571)270-5417. The examiner can normally be reached on Monday - Thursday, 8 am to 4 pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Y. S./

Examiner, Art Unit 3774

/Alvin J Stewart/

Primary Examiner, Art Unit 3774